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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,221	08/22/2003	Phillip A. Patten	704660-3001	1498

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,221	PATTEN ET AL.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *275* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *275* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/25/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on November 17, 2005 has been entered. The claims pending in this application are claim 275. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on November 17, 2005.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. New Matter

Claim 275 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "borders defining the polynucleotide segments is selected by aligning substrate nucleic acid sequences" is added to the newly amended independent claim 275. Although the specification describes that "[T]he segment borders can be chosen randomly, based on correspondence with natural exons, based on structural considerations (loops, alpha helices, subdomains, whole domains, hydrophobic core, surface, dynamic simulations), and based on correlations with genetic mapping data" (see page 38, second paragraph), the specification fails

to define or provide any disclosure to support such claim recitation because the phrase "selected by aligning substrate nucleic acid sequences" is not equal to "selected randomly".

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." (emphasis added).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 275 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 275 is rejected as vague and indefinite in view of step a) of the claim because it is unclear how borders defining the polynucleotide segments can be selected by aligning substrate nucleic acid sequences because aligning substrate nucleic acid sequences can not find the borders for the polynucleotide segments since the polynucleotide segments is smaller than substrate nucleic acid sequences. Please clarify.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 275 is rejected under 35 U.S.C. 102(e) as being anticipated by Stemmer *et al.*, (US Patent No. 5,811,238, filed on November 30, 1995).

The applied reference has a common inventor, Willem P. C. Stemmer, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 275, Stemmer *et al.*, teach a method for obtaining a chimeric polynucleotide by treating a sample comprising different double-stranded template polynucleotides wherein said different template polynucleotides contain areas of identity and areas of heterology under conditions which provide for the cleavage of said template polynucleotides into random double-stranded fragments of a desired size wherein the different double-stranded template polynucleotides are structurally-related enzymes, denaturing the resultant random double-stranded fragments contained in the treated sample into single-stranded fragments, incubating the resultant single-stranded fragments with polymerase under conditions which provide for the annealing of the single-stranded fragments at the areas of identity and the formation of a chimeric double-stranded polynucleotide sequence comprising template polynucleotide sequences, and repeating the above steps as desired (see column 6, lines 21-36 and 64-67 and column 7, lines 1-8), Stemmer *et al.*, disclose generating a plurality of defined

polynucleotide segments (ie., polynucleotide segments from different structurally-related enzymes) of substrate nucleic acid sequences (ie., polynucleotides from different structurally-related enzymes) that encode full-length enzymes, reassembling said defined polynucleotide segments in order, thereby producing the library of chimerized but defined polynucleotide sequences (ie., polynucleotides from different structurally-related enzymes) wherein each chimerized but defined polynucleotide sequence encoding a full-length enzyme as recited in the claim. Since a chimeric double-stranded polynucleotide sequence comprising template polynucleotide sequences taught by Stemmer *et al.,* still encodes an enzyme, Stemmer *et al.,* disclose said segments are reassembled in an ordered fashion as recited in the claim.

Therefore, Stemmer *et al.,* teach all limitations recited in claim 275.

Response to Arguments

In page 13, fourth paragraph bridging to page 14, first paragraph of applicant's remarks, applicant argues that "the Stemmer' 238 patent indeed does not disclose aligning substrate nucleic acid sequences to select the borders defining the polynucleotide segments".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Since, as shown in above rejection under 35 USC 112, first paragraph, the phrase "borders defining the polynucleotide segments is selected by aligning substrate nucleic acid sequences" recited in claim 275 is a new matter and should be removed from claim 275, in view of the new matter in claim 275, this rejection is maintained.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 275 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stemmer *et al.,* (WO 95/22625, published on August 24, 1995).

Regarding claim 275, Stemmer *et al.,* teach a method for obtaining a chimeric polynucleotide by treating a sample comprising different double-stranded template polynucleotides wherein said different template polynucleotides contain areas of identity and areas of heterology under conditions which provide for the cleavage of said template polynucleotides into random double-stranded fragments of a desired size, denaturing the resultant random double-stranded fragments contained in the treated sample into single-stranded fragments, incubating the resultant single-stranded fragments with polymerase under conditions which provide for the annealing of the single-stranded fragments at the areas of identity and the

formation of a chimeric double-stranded polynucleotide sequence comprising template polynucleotide sequences, and repeating the above steps as desired (see page 9, second paragraph), Stemmer *et al.,* disclose generating a plurality of defined polynucleotide segments (ie., polynucleotide segments from different templates) of substrate nucleic acid sequences (ie., polynucleotides from different templates), reassembling said defined polynucleotide segments in order, thereby producing the library of chimerized but defined polynucleotide sequences (ie., polynucleotides from different templates) as recited in the claim. Since a chimeric double-stranded polynucleotide sequence comprising template polynucleotide sequences taught by Stemmer *et al.,* still encodes a gene that has the same function of original template polynucleotides, Stemmer *et al.,* disclose said segments are reassembled in an ordered fashion as recited in the claim.

Stemmer *et al.,* do not disclose that chimerized but defined polynucleotide sequences encoding full-length enzymes as recited in claim 275. However, Stemmer *et al.,* teach that the shuffling method can be used in a population of viral genes including enzymes (see page 10, third paragraph).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have used the shuffling method taught by Stemmer *et al.,* in constructing chimerized but defined polynucleotide sequences encoding full-length enzymes using different double-stranded template polynucleotides from structurally-related enzymes as templates. One having ordinary skill in the art would have been motivated to do so because Stemmer *et al.,* suggest that their shuffling method is used in a population of viral genes including enzymes (see page 10, third paragraph). One having ordinary skill in the art at the time

the invention was made would have a reasonable expectation of success to use the shuffling method taught by Stemmer *et al.*, in different double-stranded template polynucleotides from structurally-related enzymes.

Response to Arguments

In page 14, second and third paragraphs of applicant's remarks, applicant argues that "the Stemmer' 238 patent indeed does not disclose aligning substrate nucleic acid sequences to select the borders defining the polynucleotide segments".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Since, as shown in above rejection under 35 USC 112, first paragraph, the phrase "borders defining the polynucleotide segments is selected by aligning substrate nucleic acid sequences" recited in claim 275 is a new matter and should be removed from claim 275, in view of the new matter in claim 275, this rejection is maintained.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claim is allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Frank Lu
Primary Examiner
February 3, 2006